INPLASY PROTOCOL

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Review Stage at time of this submission: **Data extraction.**

Conflicts of interest:
The lead reviewer (JB) didn't give talks on any topic at workshops, seminars. The other authors declare that they have no known conflicts of interest.

Alprostadil Combined with Tripterygium Glycosides in the Treatment of Diabetic nephropathy：A Systematic Review and Meta-analysis

Tian, HC[1]; Ren, JJ[2]; Zhang, MZ[3].

Review question / Objective: **Participants：the patients who were diagnosed in Diabetic Nephropathy; Iinterventions: the Experimental group: (Alprostadil 10ug +0.9%Nacl 100ml iv qd) +Tripterygium 20mg po tid; Comparisons：the Control group: Alprostadil 10ug +0.9%Nacl 100ml iv qd; Outcomes: 24-hour urine protein(24h Upro), blood urea nitrogen (BUN), albumin(ALB), serum creatinine(Scr), clinical efficacy and the occurrence of serious adverse events.**
Condition being studied: **Chinese herbal medicine,Diabetic Nephropathy.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 August 2020 and was last updated on 15 August 2020 (registration number INPLASY202080063).

INTRODUCTION

Review question / Objective: **participants：the patients who were diagnosed in Diabetic Nephropathy; Iinterventions: the Experimental group :(Alprostadil 10ug +0.9%Nacl 100ml iv qd)+Tripterygium 20mg po tid; Comparisons：the Control group: Alprostadil 10ug +0.9%Nacl 100ml iv qd;Outcomes: 24-hour urine protein(24h Upro),blood urea nitrogen (BUN), albumin(ALB), serum creatinine(Scr),**

clinical efficacy and the occurrence of serious adverse events.

Rationale: In recent years,Chinese herbal medicine(Tripterygium Glycosides) has been widely used in the treatment of Diabetic Nephropathy,It has the characteristics of multichannel and multitarget. It can improve the curative effect of routine western medicine treatment, improve lipid metabolism, reduce blood viscosity, improve hemorheology and renal hemodynamics, reduce inflammatory reaction, inhibit the excretion of proteinuria, delay the damage of renal function and protect renal function.

Condition being studied: Chinese herbal medicine,Diabetic Nephropathy.

METHODS

Search strategy: 1 alprostadil ,2 PGE1alpha.ti, ab. ,3 PGE1. ti, ab., 4 Lipo-PGE1. ti, ab. ,5 Prostavasin. ti, ab. ,6 Prostin VR ti, ab. ,7 Or 1-6 ,8 Tripterygium ,9 Tripterygium wilfordii ti, ab ,10 Thundergod Vine ti, ab, 11 Leigong Teng ti, ab ,12 Or 8-11 ,13 Diabetic nephropathy, 14 Diabetic Kidney Disease ti, ab ,15 Kimmelstiel Wilson Syndrome ti, ab, 16 Nodular Glomerulosclerosis ti, ab ,17 DKD ti, ab, 18 Or 13-17 ,19 Randomized controlled trial. pt. ,20 Randomized. ab. ,21 Placebo. ab. ,22 Or 19-21 ,23 7 or 12 ,24 23 and 18 and 22.

Participant or population: 3 (HuichuanTian), (Jiajun Ren), (Meilan Zhang).

Intervention: Experimental group: (Alprostadil 10ug +0.9%Nacl 100ml iv qd) +Tripterygium 20mg po tid; During the whole treatment process,All of them were given low salt, low protein and suitable food for diabetic patients.The patients were fasting with insulin or oral hypoglycemic drugs.The blood glucose was controlled at ≤ 8 mmol / L and 2 hours after meal Under the condition of ≤ 11 mmol / L.

Comparator: Control: Alprostadil 10ug +0.9%Nacl 100ml iv qd; During the whole treatment process,All of them were given low salt, low protein and suitable food for diabetic patients.The patients were fasting with insulin or oral hypoglycemic drugs.The blood glucose was controlled at ≤ 8 mmol / L and 2 hours after meal Under the condition of ≤ 11 mmol / L.

Study designs to be included: randomized controlled trial (RCT), Participants: Patients with DN were diagnosed. The diagnosis of diabetes is in accordance with the diag.

Eligibility criteria: efficiency: After treatment, the symptoms were significantly improved, and 24h urinary albumin returned to normal level, or 24-hour urinary protein was decreased over 50% . This is the effective target.

Information sources: We searched Pubmed, Embase, the Cochrane Library, China National Knowledge Infrastructure (CNKI), Wanfang Data knowledge service platform (Wanfang Data), Chinese Scientific Journal Database (VIP), and Clinical Trial for randomized controlled trials (RCTs) of PGE1 combine with TG in the treatment of DN, including results from the foundation of each database until August 5, 2020.

Main outcome(s): PRO:24h urine protein ; After treatment, the symptoms were significantly improved, and 24h urinary albumin returned to normal level, or 24-hour urinary protein was decreased over 50% . This is the effective target.

Additional outcome(s): Scr:The difference between the two groups(Scr in Experimental group and control group)was statistically significant ; BUN:The difference between the two groups(BUN in Experimental group and control group)was statistically significant ; ALB:The difference between the two groups(ALB in Experimental group and control group)was statistically significant.

Data management: This meta-analysis was carried out using RevMan5.4 software.

Quality assessment / Risk of bias analysis: Assessed :methods of randomisation,

allocation concealment, blinding of outcome, selective report. assessment will be done at outcome level. using the cochrane risk of bias tool to assess. 3 people will be involved in the quality assessment. when Huichuan Tian has disagreement with Jiajun Ren , another senior doctor (Meilan Zhang) make the final judgment and decision.

Strategy of data synthesis: Design data extraction table according to Pico principle, extract the basic information of the included literature. the minimum number of studies is 40. effective rate, PRO, Scr, BUN, ALB, TG, will be synthesised. risk ratios for individual studies will be combined using a random effects meta-analysis.

Subgroup analysis: The rationale for the investigation: the time for each experimental group is different. 40% of the time of teatment to experimental group is less than 2month(4weeks-8weeks), another 60% of the experimental group is 2 months to 3month(9weeks-12weeks). Each group should be randomised trial, intervention type as Alprostadil Combined with Tripterygium Glycosides and only Alprostadil . Details of the planned analytic : x2 test was used to test the heterogeneity among the studies. If the heterogeneity test showed that there was no heterogeneity among the studies or the heterogeneity was small($I^2$0.1), select the fixed effect analysis model; if ($I^2 \geq 50\%$, $P \leq 0.1$), elect the random effects analysis model.

Sensibility analysis: If there is obvious heterogeneity between a group of studies, the reasons for the heterogeneity should be explored from multiple aspects, such as the characteristics of the research object, the degree of variation of intervention measures, and sensitivity analysis or subgroup analysis should be conducted when necessary to explain the heterogeneity.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Alprostadil, Tripterygium Glycosides, Diabetic nephropathy, meta-analysis, Systematic Review.

Contributions of each author:
Author 1 - Huichuan Tian.
Author 2 - Jiajun Ren.
Author 3 - Meilan Zhang.